

**To:** Rodan, Bruce[rodan.bruce@epa.gov]; Yamada, Richard (Yujiro)[yamada.richard@epa.gov]  
**Cc:** Bahadori, Tina[Bahadori.Tina@epa.gov]  
**From:** Orme-Zavaleta, Jennifer  
**Sent:** Tue 1/2/2018 6:57:06 PM  
**Subject:** RE: Federal Register Notices for your review and signature

Helpful, thanks

Who is reviewing the protocol via intraagency?

Jennifer Orme-Zavaleta, PhD

Principal Deputy Assistant Administrator for Science

USEPA Office of Research and Development

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[orme-zavaleta.jennifer@epa.gov](mailto:orme-zavaleta.jennifer@epa.gov)

**From:** Rodan, Bruce  
**Sent:** Tuesday, January 02, 2018 1:11 PM  
**To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>  
**Cc:** Bahadori, Tina <Bahadori.Tina@epa.gov>  
**Subject:** FW: Federal Register Notices for your review and signature

Jennifer, Richard,

I spoke with NCEA/Sam to clarify some of the responses (and cc'ing Tina):

1. There is a detailed Systematic Review Template that is currently being reviewed intraAgency, comments due Jan 12.
2. This FRN essentially adds the “chloroform” title/some details to the systematic review template/future boilerplate. NCEA will resolve intraAgency comments on the template and match/incorporate in the chloroform FRN (and anticipate publication soon thereafter).
3. The chloroform FRN is intended as important input to the Feb NAS meeting, demonstrating that IRIS is indeed adopting the NAS recommendations into its business (absent their ability to get out the Formaldehyde draft).
4. OCSPP has been engaged in the template review/comments, but they may not be aware that there is a chloroform FRN pending [NB: Chloroform is an Office of Water requested IRIS chemical]

Bruce D. Rodan

Associate Director for Science

U.S. EPA, Office of Research and Development

**From:** Jones, Samantha

**Sent:** Tuesday, January 2, 2018 12:35 PM

**To:** Thayer, Kris <[thayer.kris@epa.gov](mailto:thayer.kris@epa.gov)>; Rodan, Bruce <[rodan.bruce@epa.gov](mailto:rodan.bruce@epa.gov)>; Bahadori, Tina <[Bahadori.Tina@epa.gov](mailto:Bahadori.Tina@epa.gov)>; D'Amico, Louis <[DAmico.Louis@epa.gov](mailto:DAmico.Louis@epa.gov)>

**Cc:** Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>

**Subject:** RE: Federal Register Notices for your review and signature

Hi all, a few additional notes from me... in green.

Thanks,

Samantha

**Samantha Jones, PhD**

**NCEA Associate Director for Health (acting)**

**HHRA Interim Deputy National Program Director**

USEPA, ORD/NCEA

202-564-6794

**From:** Thayer, Kris

**Sent:** Tuesday, January 2, 2018 11:58 AM

**To:** Jones, Samantha <[Jones.Samantha@epa.gov](mailto:Jones.Samantha@epa.gov)>; Rodan, Bruce <[rodan.bruce@epa.gov](mailto:rodan.bruce@epa.gov)>; Bahadori, Tina <[Bahadori.Tina@epa.gov](mailto:Bahadori.Tina@epa.gov)>; D'Amico, Louis <[DAmico.Louis@epa.gov](mailto:DAmico.Louis@epa.gov)>

**Cc:** Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>

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Yes, Happy New Year!

Responses below...some of them are long (sorry!), so please let me know if they are not clear. I'm in UK until Jan 4 but could certainly be available for a phone call if needed

Lou/Sam – I've flagged a few comments in blue below for you to "fact check" my response.

**From:** Rodan, Bruce

**Sent:** Tuesday, January 2, 2018 11:26 AM

**To:** Bahadori, Tina <[Bahadori.Tina@epa.gov](mailto:Bahadori.Tina@epa.gov)>; Thayer, Kris <[thayer.kris@epa.gov](mailto:thayer.kris@epa.gov)>

**Cc:** Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>

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Tina, Kris,

Hi. Welcome to the New Year! Jennifer, Richard, and I spoke this morning, and had a few process questions regarding the Chloroform protocol FRN, since it contains quite a deal of information on the Systematic Review Protocol and decision language – and appears to be of major importance in the lead-up to an NAS review:

- What has been the intraAgency process so far on the chloroform FRN? There has not been any interagency review of the FR notice itself (this would not be standard practice – Lou/Sam correct me if I’m wrong), but the IAP was presented in public and there were no major changes based on the SAB or public comments.

Lou/Sam Kris is correct. FRNs do not go through an intraAgency review. Because it was a new format document, the chloroform IRIS Assessment Plan (IAP) underwent intraAgency and ORD review before being released to the public.

- If not circulated intraAgency as an FRN, what has been the IntraAgency process on the systematic review protocol and standard decision tables/language in the Chloroform FRN? The protocol is a new document, so there is no precedence. We have shared for Agency comment the template protocol on which chloroform is based. Of course, the template protocol was developed based on considering comments on the IRIS Handbook. We are expecting Agency comments on the template protocol by January 12<sup>th</sup>. Thus, prior to public posting we would be able to update the chloroform protocol as needed based on comments received on the template. Moving forward, the protocols for “new starts” will be largely boiler plate except for the IAP portion, which is reviewed separately. Thus, I’m not sure we ALWAYS need to share the protocol for Agency comment. However, given that these documents are still new we could disseminate the chloroform protocol for Agency comment. BUT, before committing to that course of action can we see the Agency comments we get by January 12<sup>th</sup> on the template protocol? If they are not major, can we leave open the option of NOT getting Agency comment on the chloroform protocol? As an aside, we have a meeting on January 16 with our Agency partners to discuss the handbook and status of the template protocol. So we can indicate our course of action on the chloroform protocol at that time.

•□□□□□□ A substantial proportion of the FRN reminds me of the detail in the IRIS SOPs. There was some intraAgency angst in the past regarding the language being proposed to summarize non-cancer findings/classifications. This FRN has a detailed “Framework for classification of strength of evidence from studies in humans”, as well as Frameworks for evaluating the strength of PBPK modeling. Were these the areas of intraAgency concern, and have these concerns been addressed agency-wide? We will find out. The angst we heard previously was focused on use of descriptors for hazard, not so much the strength of evidence for within stream conclusions, such as human. I don’t believe anyone had issues with the PBPK modeling approach during review of the Handbook. However, we will find out if there are concerns when we get comments on the template protocol January 12.

•□□□□□□ Has this document and/or the information contained therein been circulated interagency? Is this part of the IRIS multistep process? No, and I don’t know if we want to go there. I believe the past practice is for agencies to comment during the public comment period. This was the case for the IAPs and would be the case here too. Lou/Sam, correct me if I’m wrong. That said, we are trying to work with appropriate technical experts at other agencies on the IAP (and protocol if needed), but this is distinct from the formal interagency review. Kris is correct. These items like the IAP and the protocol are considered part of our preliminary assessment materials we have been releasing to the public since 2013. These preliminary materials and associated activities fall under step 1 of the 7-step IRIS process and help with building the development of the draft assessment, which when completed is taken through the remaining steps of the IRIS process, including intraAgency, interAgency review, public comment, peer review, and so on.

•□□□□□□ More specifically, has OCSPP been apprised of these protocols during intraAgency review or subsequently? Could this FRN come as a surprise to OCSPP or another Program? Yes OCSPP should be aware of the protocols, we shared the HBDC and template protocol with OCSPP as part of our broader Agency sharing. Also, we have indicated our intent to post for public comment the protocol following the IAP presentation (but in public and to the Agency). The chloroform IAP was presented in September. So, this should not be a surprise. We could also announce the intent to post this protocol for public comment at our January 16 Agency meeting on the handbook/template protocol.

Thanks

Bruce D. Rodan

Associate Director for Science

U.S. EPA, Office of Research and Development

**From:** Bahadori, Tina

**Sent:** Thursday, December 21, 2017 7:07 AM

**To:** Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>

**Cc:** Ross, Mary <[Ross.Mary@epa.gov](mailto:Ross.Mary@epa.gov)>; D'Amico, Louis <[DAmico.Louis@epa.gov](mailto:DAmico.Louis@epa.gov)>; Soto, Vicki <[Soto.Vicki@epa.gov](mailto:Soto.Vicki@epa.gov)>; Shams, Dahnish <[Shams.Dahnish@epa.gov](mailto:Shams.Dahnish@epa.gov)>; Thayer, Kris <[thayer.kris@epa.gov](mailto:thayer.kris@epa.gov)>; Christian, Megan <[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)>; Kuhn, Kevin <[Kuhn.Kevin@epa.gov](mailto:Kuhn.Kevin@epa.gov)>; Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>; Rodan, Bruce <[rodan.bruce@epa.gov](mailto:rodan.bruce@epa.gov)>; Fleming, Megan <[Fleming.Megan@epa.gov](mailto:Fleming.Megan@epa.gov)>

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Good Morning Jennifer and Richard,

We are preparing to release for public comment an IRIS Assessment Plan for (non-radiological) Uranium and a Protocol for Chloroform. Both of these were among the portfolio of 'targeted' assessment products presented to the SAB-CAAC in September as examples of assessments we can do relatively quickly because the partner need is focused and 'bounded.' For each chemical, we have attached the following documents – C and U in the name of the attachment denote Chloroform and Uranium respectively:

1. A memo that summarizes the effort for you
2. Action Information that accompanies the FR Notice
3. The FR Notice
4. FRN Approval Form (**requires Richard's signature**)
5. The document – an Assessment Plan or a Protocol

If you have any questions or would like additional information, please do not hesitate to give me a call.

Many thanks,

Tina

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**Tina Bahadori, Sc.D.**

**Director, National Center for Environmental Assessment (EPA/ORD/NCEA)**

**National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)**

**RRB Room 71210; Telephone: 202-564-7903; Mobile: 202-680-8771**